SEP 2 2 2006

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K062204

COMPANY/CONTACT PERSON

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DATE PREPARED

July 27, 2006

DEVICE NAME

Trade Name:	ARCHITECT Cortisol
Common Name:	Fluorometric, Cortisol
Device Classification:	21 CFR 862.1205; Cortisol (hydrocortisone and hydroxycorticosterone) test system; Class II

Trade Name:	ARCHITECT Cortisol Calibrators
Common Name:	Calibrator, Secondary
Device Classification:	21 CFR 862.1150; Cortisol (calibrator) test system; Class II

Intended use

ARCHITECT® Cortisol is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of cortisol in human serum, plasma or urine on the ARCHITECT *i* System. The ARCHITECT Cortisol assay is intended for use as an aid in the diagnosis and treatment of adrenal disorders.

The ARCHITECT Cortisol Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of cortisol in human serum, plasma or urine.

Legally marketed device to which equivalency is claimed

AXSYM® CORTISOL REAGENTS AND CALIBRATORS (K033731)

DESCRIPTION OF DEVICE

The ARCHITECT Cortisol assay is a delayed one-step immunoassay for the quantitative determination of cortisol in human serum, plasma or urine using CMIA technology with flexible assay protocols, referred to as Chemiflex®.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device ARCHITECT Cortisol	**Predicate** AxSYM Cortisol
Intended Use (Reagents)	ARCHITECT Cortisol is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of cortisol in human serum, plasma or urine on the ARCHITECT *i* System. The ARCHITECT Cortisol assay is intended for use as an aid in the diagnosis and treatment of adrenal disorders.	The Cortisol assay is a Fluorescence Polarization Immunoassay (FPIA) for the quantitative measurement of cortisol in human serum, plasma and urine on the AxSYM System to aid in the diagnosis and treatment of adrenal disorders.
Intended Use (Calibrators)	The ARCHITECT® Cortisol Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of cortisol in human serum, plasma or urine.	The AxSYM Cortisol Calibrators are for the calibration of the Abbott AxSYM Cortisol System to aid in the diagnosis and treatment of adrenal disorders.
Indications for Use	The results obtained are used to aid diagnosis and treatment of adrenal disorders.	The results obtained are used to aid diagnosis and treatment of adrenal disorders.
Methodology	Heterogeneous chemiluminescent microparticle immunoassay (CMIA).	Fluorescence Polarization Immunoassay (FPIA) technology.
Reagent Components	Two (2) reagent system: • Microparticle Reagent with Anti-Cortisol (mouse) coated Microparticles in buffer with protein stabilizer, Proclin 300 and sodium azide. • Conjugate Reagent with Cortisol acridinium labeled conjugate in buffer with surfactant stabilizer and Proclin 300.	Three (3) reagent system: • Pretreatment Solution (P) Surfactant in TRIS buffer and sodium azide. • Cortisol Antiserum (Mouse and Goat) in buffer with protein stabilizer and Sodium azide. • Cortisol Fluorescein Tracer in buffer containing surfactant and stabilizers, and Sodium azide.
Calibration	ARCHITECT Cortisol Calibrators – six levels	AxSYM Cortisol Calibrators – six levels

SUMMARY OF CLINICAL TESTING

Linearity

Linearity by Dilution was determined by a study based on the NCCLS guideline *EP6- A: Evaluation of the Linearity of Quantitative Measurement.*

A regression analysis plot of recovered cortisol against dilution factor was constructed.
The p-values and regression standard error (Reg SE) were examined for each pool. The second order polynomial regression was chosen and the percent deviation from linearity (%DLP) calculated from the predicted second order polynomial regression and compared to the predicted first order polynomial (linear) regression.

65 ug/dL Serum Pool

Dilution	Result ug/dL	Predicted 1st ug/dL	Predicted 2nd ug/dL	difference ug/dL	% DLP
100%	N/A	N/A	N/A	N/A	N/A
90%	65.85	64.60	66.17	-1.6	-2%
80%	58.41	57.28	57.80	-0.5	-1%
70%	49.69	49.96	49.70	0.3	1%
60%	41.92	42.64	41.85	0.8	2%
50%	33.69	35.31	34.27	1.0	3%
40%	26.74	27.99	26.95	1.0	4%
30%	19.72	20.67	19.89	0.8	4%
20%	14.02	13.35	13.09	0.3	2%
10%	6.53	6.03	6.55	-0.5	-8%
0%	-0.04	-1.30	0.27	-1.6	Target ± 20% Deviation

8 ug/dL Serum Pool

Dilution	Result ug/dL	Predicted 1st ug/dL	Predicted 2nd ug/dL	difference ug/dL	% DLP
100%	7.79	7.66	7.81	-0.2	-2%
90%	7.01	6.86	6.92	-0.1	-1%
80%	5.87	6.07	6.06	0.0	0%
70%	5.27	5.27	5.21	0.1	1%
60%	4.43	4.48	4.39	0.1	2%
50%	3.68	3.69	3.58	0.1	3%
40%	2.83	2.89	2.80	0.1	3%
30%	2.03	2.10	2.04	0.1	3%
20%	1.16	1.30	1.29	0.0	1%
10%	0.49	0.51	0.57	-0.1	-12%
0%	-0.01	-0.28	-0.13	-0.2	Target ± 20% Deviation

Accuracy

Accuracy by Recovery was determined by spiking cortisol into human serum and urine to achieve concentrations across the range of the assay. The samples were analyzed in triplicate with the ARCHITECT Cortisol assay.

Serum

	Donor 1			Donor 2			Donor 3		
	Observed	Expected	% Recovery	Observed	Expected	% Recovery	Observed	Expected	% Recovery
Unspiked	8.1	N/A	N/A	13.7	N/A	N/A	12.6	N/A	N/A
Spiked 5 ug/dL	12.5	12.7	98.5	17.8	18.2	97.6	16.4	17.1	95.7
Spiked 10 ug/dL	15.7	17.3	90.9	21.2	22.8	93.2	20.4	21.7	94.1
Spiked 20 ug/dL	23.7	26.4	89.6	28.7	31.8	90.2	28.4	30.8	92.3
Spiked 40 ug/dL	39.5	44.8	88.2	43.0	49.9	86.1	43.2	48.9	88.3
									Target Recovery 100 ± 15%

Urine

	Donor 1			Donor 2			Donor 3		
	Observed	Expected	% Recovery	Observed	Expected	% Recovery	Observed	Expected	% Recovery
Unspiked	5.7	N/A	N/A	22.0	N/A	N/A	11.9	N/A	N/A
Spiked 5 ug/dL	10.4	10.3	100.9	25.1	26.4	94.9	16.1	16.4	97.9
Spiked 10 ug/dL	14.0	14.9	93.8	29.5	30.9	95.5	19.3	21.0	91.9
Spiked 20 ug/dL	22.2	24.1	92.0	34.6	39.8	87.0	27.6	30.1	91.7
Spiked 40 ug/dL	36.0	42.6	84.6	52.0	57.6	90.3	41.2	48.3	85.3
									Target Recovery 100 ± 20%

Sensitivity

1) The limit of blank (LoB) and the LoD were determined with guidance from CLSI guideline NCCLS *EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline* using proportions of false positives (α) less than 5% and false negatives (β) less than 5%. These determinations were performed using 60 blank and 120 low level samples.

ARCHITECT i2000	LoB= 0.234 µg/dL	and	LoD= 0.401ug/dL
ARCHITECT i2000SR	LoB= 0.125 µg/dL	and	LoD= 0.255ug/dL

An assay claim of LoD=0.8ug/dL is supported by the data.

2) The functional sensitivity of the ARCHITECT Cortisol assay was determined with guidance from CLSI guideline NCCLS EP17-A.

At the upper 95% confidence limit, the lowest serum value exhibiting a 20% CV was calculated to be 0.8µg/dL. At the upper 95% confidence limit, the lowest urine value exhibiting a 20% CV was calculated to be 1µg/dL.

Method Comparison

The studies were conducted according to CLSI Guideline NCCLS *EP9: Method Comparison and Bias Estimation Using Patient Samples* to compare accuracy of recovery of Cortisol in serum and urine assayed by the ARCHITECT Cortisol assay to the Abbott AxSYM® Cortisol assay.

The results of the Method comparison study met the design goals and acceptance criteria.

Precision

A precision study was performed using the National Committee for Clinical Laboratory Standards (NCCLS) guideline *EP5-A2: Evaluation of Precision Performance of Clinical Chemistry Devices.*

Sample	Instr.	Reagent Lot	n	Mean Conc. ug/dL	Within Run		Between Day		Total	
					SD	%CV	SD	%CV	SD	%CV
MCC 1	I2000	A	80	3.8	0.1369	3.6	0.1315	3.4	0.1898	5.0
	I2000SR	B	80	4.0	0.1924	4.8	0.0000	0.0	0.2321	5.8
MCC 2	I2000	A	80	16.6	0.4300	2.6	0.4071	2.5	0.6184	3.7
	I2000SR	B	80	17.3	0.4000	2.3	0.5459	3.2	1.3228	7.7
MCC 3	I2000	A	80	30.3	0.8739	2.9	0.6784	2.2	1.1695	3.9
	I2000SR	B	80	31.0	0.6344	2.1	1.1223	3.6	1.3178	4.3
Serum panel 1	I2000	A	80	2.9	0.0829	2.9	0.0000	0.0	0.1140	4.0
	I2000SR	B	80	2.9	0.1601	5.5	0.0835	2.9	0.1806	6.2
Serum panel 2	I2000	A	80	39.8	0.9526	2.4	0.0000	0.0	1.0065	2.5
	I2000SR	B	80	41.0	1.0822	2.6	0.4470	1.2	1.2947	3.2
Serum panel 3	I2000	A	80	53.3	1.7061	3.2	0.2887	0.5	1.7303	3.3
	I2000SR	B	80	55.8	1.5047	2.7	0.9540	1.7	1.8730	3.4
Urine panel 1	I2000	A	80	2.4	0.1270	5.3	0.0545	2.3	0.1482	6.2
	I2000SR	B	80	2.7	0.1636	6.1	0.0463	1.7	0.1700	6.4
Urine panel 2	I2000	A	80	14.5	0.3927	2.7	0.0000	0.0	0.5875	4.1
	I2000SR	B	80	15.9	0.6039	3.8	0.3916	2.5	0.7198	4.5
Urine panel 3	I2000	A	80	36.8	1.0509	2.9	0.5742	1.6	1.3916	3.8
	I2000SR	B	80	40.6	1.5605	3.9	0.3012	0.7	1.5893	3.9
Urine panel 4	I2000	A	80	49.0	2.8402	5.8	0.0000	0.0	2.8402	5.8
	I2000SR	B	80	53.7	3.1812	5.9	0.0000	0.0	3.1812	5.9
									Acceptance Criteria < 10% total CV serum <20% total CV urine	

Interferences

Interference studies were conducted using CLSI Guideline NCCLS *EP7-A2: Interference Testing in Clinical Chemistry.*

A. Endogenous Substances

1) Serum

Interfering Substance	Interferent Concentration	N	Target µg/mL	Mean Recovery µg/mL	% Interference
Bilirubin	20mg/dL	3	5.1	5.3	+3.9
			28.4	29.8	+4.9
Hemoglobin	10g/dL	3	5.3	5.2	-1.9
			29.4	30.6	+0.3
Triglyceride	2000 mg/dL	3	5.1	4.7	-7.8
			28.8	27.1	-5.9
Total Protein	10 g/dL	3	10.9	11.4	+4.6
			34.2	38.7	+13.2
Total Protein	3 g/dL	3	8.1	9.0	+11.1
			31.4	29.3	-6.7

2) Urine

% Interferant	Concentration of Interferant	Mean Recovery Endogenous Cortisol only	% Interference	Mean Recovery Cortisol Spiked	% Interference
Unaltered Urine Control	N/A	4.9	N/A	36.9	N/A
Mock spike Control	N/A	4.6	N/A	37.9	N/A
Protein	1000mg/dL	5.1	-4.1	38.6	-4.6
Creatinine	5mmol/L	4.5	2.2	37.0	2.4
Urea	350mmol/L	4.6	6.1	36.3	1.6
Glucose	5mmol/L	4.5	2.2	37.6	0.8
NaCl	1000mmol/L	5.0	-2.0	38.1	-3.3
Boric Acid	1%	4.8	2.0	37.6	-1.9

B. HAMA

As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample, which could cause falsely elevated results.

Sample	Native Cortisol ug/dL	Spiked with Cortisol ug/dL	Spiked with cortisol-free serum ug/dL	% Recovery
1	4.9	10.1	4.7	101.0
2	11.2	21.8	10.2	102.8
3	11.5	21.2	10.6	98.1
4	8.7	13.9	8.4	101.5
5	6.6	11.7	6.4	100.0
6	19.9	29.7	18.6	100.3
7	18.3	28.8	17.9	99.7
8	9.7	14.7	9.4	100.0
HAMA-1	8.6	13.8	8.5	100.0
HAMA-2	8.0	13.5	8.5	97.8
Grand Mean % Recovery			Acceptance Criteria 100±15%	**100.1**

C. Rheumatoid Factor (RF)

Ten positive RF patient samples were assayed for cortisol concentration.

Sample	Native Cortisol ug/dL	Spiked Cortisol ug/dL	Spiked with cortisol-free serum ug/dL	% Recovery
1	11.1	19.4	10.5	92.4
2	5.0	10.0	4.9	90.9
3	11.0	20.5	11.3	94.0
4	34.0	41.8	33.6	94.8
5	17.3	24.9	16.2	93.3
6	5.4	10.9	5.5	94.0
7	14.1	21.8	13.8	89.7
8	3.0	8.6	2.9	95.6
9	23.8	31.8	23.4	93.8
10	13.8	24.1	13.1	102.1
Grand Mean % Recovery			Acceptance Criteria 100±15%	**94.1**

D. Anticoagulants

Studies were conducted to determine the performance characteristics of the assay for both serum and plasma samples containing Cortisol.

The results indicate that there is no significant difference between the recovery of Cortisol in serum or plasma. The collection tubes evaluated show no adverse effects on the recovery of Cortisol, within the experimental error for the spiking study.

A claim for assay application to both serum and plasma samples is thus supported.

Specificity

Cortisol was spiked into cortisol free human serum at approximately 12ug/dL. Cross reactant stock concentrates were prepared in solvent and spiked into aliquots of the 12ug/dL cortisol serum to achieve cross reactant concentrations of 100 or 1000ug/dL. A control aliquot was prepared for each solvent system by spiking the solvent into the 12ug/dL cortisol serum at the same volume used with the cross reactant stocks.

Cross Reactant	Test conc ug/dL	% Cross Reactivity
11-beta-OH-progesterone	1000	0.2
11-deoxycorticosterone	100	0.1
11-deoxycortisol	100	2.1
17-alpha-OH Pregnenolone	1000	0.1
17-OH-progesterone	1000	0.6
6-beta-OH cortisol	1000	0.2
6-methyl- prednisolone	1000	0.1
Aldosterone	1000	0.0
Beclomethasone	1000	0.0
beta-cortol	1000	0.0
beta-cortolone	1000	0.0
Beta-Estradiol	1000	0.0
beta-Sitosterol	1000	0.0
Budesonide	1000	0.0
Canrenone	1000	0.1
Corticosterone	1000	0.9
Cortisol-21-glucuronide	1000	0.2
Cortisone	1000	2.8
Dexamethasone	1000	0.0
DHEA	1000	0.0
DHEA-S	1000	0.0
Estriol	1000	0.0
Estrone	1000	0.0
Fludrocortisone	100	36.8
Fluticasone Propionate	1000	0.0
Medroxy Progesterone Acetate	1000	0.0
Mometasone	1000	0.0
Prednisolone	100	12.5
Prednisone	1000	0.6

Cross Reactant	Test conc ug/dL	% Cross Reactivity
Pregnanediol	1000	0.0
Pregnanetriol	1000	0.0
Pregnenolone	1000	0.0
Progesterone	1000	0.1
Spironolactone	1000	0.0
Testosterone	1000	0.1
Tetracycline	1000	0.0
Tetrahydrocortisol	1000	0.6
Triamcinolone	1000	0.4

On-Board Stability

1) Calibration Curve stability

Calibration curve stability of a period of 30 days is supported by the data.

2) Reagent On-Board Stability

A 30 day on-board reagent stability claim is supported by the data.

CONCLUSION

The ARCHITECT Cortisol assay has been shown to be substantially equivalent to the Abbott AxSYM Cortisol assay through the following performance testing: The performance testing verifies that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 19 2006

Mr. Jack Rogers
Manager of Regulatory Affairs
Seradyn, Inc.
7998 Georgetown Rd., Suite 1000
Indianapolis, IN 46268

Re: k062204
Trade/Device Name: ARCHITECT Cortisol
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: JFT, JIT
Dated: July 31, 2006
Received: August 3, 2006

Dear Mr. Rogers,

This letter corrects our substantially equivalent letter of 9/22/2006.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062204

Device Name: ARCHITECT Cortisol

Indications for Use:

ARCHITECT Cortisol is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of cortisol in human serum, plasma or urine on the ARCHITECT *i* System. The ARCHITECT Cortisol assay is intended for use as an aid in the diagnosis and treatment of adrenal disorders.

The ARCHITECT Cortisol Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of cortisol in human serum, plasma or urine.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K062204-1